**IMPORTANT NOTES:**

1. Clinical Physics does not need to approve the use of Trust-owned medical devices that are already in use and used as intended.
2. Clinical Physics does not assess electronic/non-medical devices, such as mobile phones, tablets, laptops or e-diaries etc. However, if these devices are connected to a medical device or are used for a medical purpose, a clinical physics review is required. This includes the use of Apps.
3. All commercial studies will be subject to a fee of for a Clinical Physics review/approval dependent on the number of devices. Please see [http://www.jrmo.org.uk/media/jrmo/docs/performing-research/research-facilities/Standardised\_R&D\_costs[1].pdf](http://www.jrmo.org.uk/media/jrmo/docs/performing-research/research-facilities/Standardised_R%26D_costs%5B1%5D.pdf). Please note that this fee may need to be revised depending on the study type/intended use of the device/number of devices or complexity of devices. The research team will be informed if the fee needs to be revised.
4. **Important:** Have you attached the following documentation to support the feasibility form? Please tick:

[ ]  Study protocol

[ ]  IRAS form/project study information/ethics question set

[ ]  Trial contract/equipment indemnity cover documentation e.g. CTA/completed MIA where applicable

[ ]  Equipment manuals – technical and user manuals

[ ]  CE/UKCA certificates for CE/UKCA-marked equipment

[ ]  For clinical investigations, the MHRA’s no-objection letter

[ ]  Where appropriate, investigator’s brochure for device-centred studies

[x]  Where appropriate, technical documentation for proof-of-concept/Pre-CE/UKCA-marking studies

Please send this completed form and the relevant study documentation to research.clinicalphysics@nhs.net

1. **Important:** On review completion, any equipment identified as requiring electrical safety testing (EST) or visual checks must be delivered to the site workshop by the research team. Once tested, please ensure that the equipment job request number, (which will be provided by the site workshop) along with a completed copy of this form is emailed to research.clinicalphysics@nhs.net.
2. **Study / Research Details**

|  |  |  |
| --- | --- | --- |
| **1.1.**  | **Short Title/Acronym:** |  |
| **1.2.** | **Full study title:** |  |
| **1.3.** | **IRAS Number:** |  |
| **1.4.** | **Protocol version no.:** |  |
| **1.5.** | **Commercial /** **Non-Commercial Study:** |  |
| **1.6.** | **Has the Clinical Physics fee been included in the contract?** **See** [**http://www.jrmo.org.uk/media/jrmo/docs/performing-research/research-facilities/Standardised\_R&D\_costs[1].pdf**](http://www.jrmo.org.uk/media/jrmo/docs/performing-research/research-facilities/Standardised_R%26D_costs%5B1%5D.pdf)**.**  |  |
| **1.7.** | **Sponsor:** |  |
| **1.8.** | **Do you have REC/HRA approval?** |  |
| **1.9.** | **Trial team group email (shared)** |  |
| **1.10** | **Trial team coordinator name:** |  |
| **1.11** | **PI/CI (name and email):** |  |
| **1.12** | **Barts Health hospital site(s) where study will be performed:** | [ ]  St. Bartholomew’s Hospital (SBH)[ ]  The Royal London Hospital (RLH)[ ]  Whipps Cross Hospital (WXH)[ ]  Newham University Hospital (NUH)[ ]  Mile End Hospital (MEH) |
| **1.13** | **Study Start Date:** |  |
| **1.14** | **Study End Date:** |  |

1. **Research device details**

| **No.** | **Criteria** | **Device 1** | **Device 2** | **Device 3** | **Device 4** | **Device 5** | **Add columns for additional devices or amendments** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **2.1.** | **Device Type** |  |  |  |  |  |  |
| **2.2.** | **Manufacturer** |  |  |  |  |  |  |
| **2.3.** | **Supplier (if different from manufacturer)** |  |  |  |  |  |  |
| **2.4.** | **Model** |  |  |  |  |  |  |
| **2.5.** | **Is the equipment currently in use and Trust owned? (Y/N)** |  |  |  |  |  |  |
| **2.6.** | **Is the equipment new? (Y/N)****If Yes, who owns the equipment (e.g. Trust, QMUL etc.)** |  |  |  |  |  |  |
| **2.7.** | **Is the equipment on loan? (Y/N)****If Yes, who is the supplier?** |  |  |  |  |  |  |
| **2.8.** | **If on loan, is the device indemnity covered by either the Master Indemnity Agreement (MIA) or the relevant Clinical Trial Agreement (CTA) – please state which agreement covers the loan** |  |  |  |  |  |  |
| **2.9.** | **Is the equipment CE/UKCA marked and licenced for the intended use? Y/N** |  |  |  |  |  |  |
| **2.10.** | **Will the equipment be used as intended as described in the manufacturer’s instructions for use? Y/N** **If No, please describe how the intended use will differ from the licenced use** |  |  |  |  |  |  |
| **2.11.** | **Estimated delivery date if equipment is new (where appropriate, please specify if the equipment is to be delivered in batches, providing the delivery date for each batch)** |  |  |  |  |  |  |
| **2.12.** | **Is the device intended to support the study or is this a device-centred study?** |  |  |  |  |  |  |
| **2.13.** | **Total no. of units to be used in study** |  |  |  |  |  |  |
| **2.14.** | **Is the equipment mains-powered or battery-powered? If mains-powered (and if known), please state the electrical safety class and rating of the device** |  |  |  |  |  |  |
| **2.15.** | **Will the equipment be connected to other medical devices? (Y/N)****If Yes, please list devices** |  |  |  |  |  |  |
| **2.16.** | **Will the equipment use consumables e.g. catheters, giving sets for pumps etc.?** |  |  |  |  |  |  |
| **2.17.** | **Will the equipment be connected to other non- medical devices e.g. phones, tablets etc.? (Y/N)****If Yes, please list devices** |  |  |  |  |  |  |
| **2.18.** | **Is there a patient data or IT connectivity aspect?** |  |  |  |  |  |  |
| **2.19.** | **Will the equipment be used in a patient’s home or other community setting? (Y/N)****If Yes, please specify where the equipment will be used.** |  |  |  |  |  |  |
| **2.20.** | **Training – will staff be trained to use the equipment?** **(Y/N)****If Y, who will provide training and where will training records be stored?** |  |  |  |  |  |  |
| **2.21.** | **Equipment maintenance/ service/repair during the study – who will provide this?** |  |  |  |  |  |  |
| **2.22.** | **If device is on loan, will the device be returned back to the supplier (Y/N)?****If No, what is the intended use of the device and for how long?**  |  |  |  |  |  |  |
| **2.23.** | **How many patients will use the device i.e. will it be one device per patient or one device for all recruited patients?** |  |  |  |  |  |  |
| **2.24.** | **If a mobile phone device/tablet is to be used, will these be provided to subjects or will they use their own personal devices?**  |  |  |  |  |  |  |
| **2.25.** | **Which app(s) will be used if a mobile phone device/tablet is to be used?** |  |  |  |  |  |  |
| **2.26.** | **Are the app(s) CE marked/UKCA marked for the intended use?** |  |  |  |  |  |  |
| **2.27.** | **Any additional information** |  |  |  |  |  |  |

1. **Applicant details**

|  |  |  |
| --- | --- | --- |
| **3.1** | **Name:** |  |
| **3.2.** | **Position:** |  |
| **3.3.** | **Contact Details:** |  |
| **3.4.** | **Form Completion Date:** |  |

1. **Clinical Physics assessment outcome – office use only**

|  |  |  |
| --- | --- | --- |
| **4.1.** | **Study type:** | Device-supporting studies:[ ]  CE/UKCA-marked above SOC.Device-centred studies:[ ]  CE/UKCA-marked clinical evaluation.[ ]  MHRA clinical investigation.[ ]  Pre-CE/UKCA marking proof-of-concept (non-MHRA) study. |
| **4.2.** | **Number of devices to be assessed/tested** |  |
| **4.3.** | **CE/UKCA-marking status of devices:** |  |
| **4.4.** | **Electrical safety classification of devices/applied parts (60601 classification)** |  |
| **4.5.** | **Applicable set-up fee:** | [ ]  Non-commercial study[ ]  Document review only[ ]  Document review and EST of up to 3 CE/UKCA-marked devices[ ]  Risk and safety assessment of 1 pre-CE/UKCA marked device[ ]  Other (with details)\*:  |
| **4.6.** | **Clinical Physics assessor name:** |  |
| **4.7.** | **Position:** |  |
| **4.8.** | **Review outcome and feedback:** |  |
| **4.9.** | **Date review completed:** |  |

*\*Note: Additional fees may apply for the assessment and testing of > 3 CE/UKCA-marked devices or > 1 pre-CE/UKCA marked device. Clinical Physics will advise accordingly and inform researchers of any additional costs.*